# Optimising thromboembolic and stroke prevention in pharmacist-managed oral anticoagulotherapy

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
05/09/2005	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
05/09/2005	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
11/03/2009	Circulatory System	

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Lyne Lalonde

#### Contact details

Équipe de recherche
Soins de première ligne
Centre de santé et de services sociaux de Laval (Cité de la Santé de Laval)
1755 René-Laennec
Local D-S145
Laval
Canada
H7M 3L9
+1 514 343 6111 ext. 5315
lyne.lalonde@umontreal.ca

# Additional identifiers

Protocol serial number UCT-58955

# Study information

#### Scientific Title

Optimising thromboembolic and stroke prevention: a randomised controlled trial of pharmacist-managed oral anticoagulotherapy

#### Acronym

**PHARMA** 

# Study objectives

Compared to the centralised care model, the integrated care model may be associated with similar anticoagulation control, similar incidence of major haemorrhagic and thromboembolic events and similar patients quality of life. However, the integrated care may represent a more efficient use of the health-care system. It may be less costly.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Cité de la Santé de Laval, Comité d'éthique et de la recherche (conditional approval of the project: 18th December 2001). Full approval as on 12th November 2002 until 11th November 2003; amendments to the protocol made on 16th September 2003. Reapprobation of the project on the following dates:

18th November 2003: reapprobation of the project until 11th November 2004 9th October 2004: reapprobation of the project until 15th September 2005 11th October 2005: reapprobation of the project until 11th November 2006

#### Study design

Randomised controlled trial

### Primary study design

Interventional

# Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Thromboembolism and stroke

#### **Interventions**

A three-year randomised controlled trial (RCT) will be conducted. All patients registering at the PMAS with a first prescription of warfarin for a minimum of six months and who agree to participate (n = 500) will be randomised to the integrated or the centralised PMAS model of care.

Integrated care model: Patients will be monitored by PMAS pharmacists until stabilisation of their international normalised ratio (INR) within their prescribed therapeutic range (six to eight weeks). Thereafter, they will be transferred to their treating physician.

Centralised care model: Patients will be monitored by PMAS for the entire duration of the study.

All patients will be followed for a total of six months. We will monitor the quality of INR control, the incidence of major thromboembolic and haemorrhagic events, the patients health-related quality of life, and direct health-care costs associated with each model of care.

#### Intervention Type

Drug

#### Phase

Not Applicable

# Drug/device/biological/vaccine name(s)

Warfarin

#### Primary outcome(s)

The percentage of time spent within the target INR range.

#### Key secondary outcome(s))

- 1. Incidence and severity of major thromboembolic and haemorrhagic events
- 2. Health-related quality of life
- 3. Direct medical-care costs

#### Completion date

31/03/2005

# Eligibility

#### Key inclusion criteria

- 1. The patient is referred to the Pharmacy Managed Anticoagulation Service (PMAS) with a prescription of warfarin for at least six months
- 2. The patient is aged 18 years and older, either sex
- 3. The patient agrees to go to the Cité de la Santé de Laval, the Centre Hospitalier Ambulatoire Régional de Laval, or one of the four Laval Centre Local de Services Communautaire for blood drawing during participation in the study (six months)
- 4. The patient lives in the Laval area
- 5. The patient is able to read and speak French or English
- 6. The patient agrees to participate in the study and has signed the informed consent form
- 7. The patient's treating physician has agreed to participate and has signed the informed consent form
- 8. It is expected that the patient will be transferred to the treating physician

## Participant type(s)

Patient

# Healthy volunteers allowed

No

## Age group

Adult

#### Lower age limit

18 years

Sex

# Key exclusion criteria

- 1. The patient participates to another study
- 2. The patient is referred to the PMAS for a pre-admission

#### Date of first enrolment

01/01/2001

#### Date of final enrolment

31/03/2005

# Locations

#### Countries of recruitment

Canada

# Study participating centre Équipe de recherche

Laval Canada H7M 3L9

# Sponsor information

#### Organisation

Cité de la Santé de Laval (Canada)

#### **ROR**

https://ror.org/041v96n47

# Funder(s)

## Funder type

Research organisation

#### Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: UCT-58955)

# Funder Name

Taro Pharmaceutical Inc. (Canada)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2008		Yes	No